Freedom of Information Summary

NADA 121-473

Supplemental New Animal Drug Application

Intervet Inc. 405 State Street PO Box 318 Millsboro, DE 19966-0318

PANACUR®-C (fenbendazole) Granules 22.2%

This supplement provides for a change from prescription (Rx) to OTC status for fenbendazole granules 22.2% packets to be marketed under the trade name PANACUR®-C.

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1. GENERAL INFORMATION

Supplemental New Animal Drug Application No.: 121-473

Sponsor: Intervet Inc.

405 State Street PO Box 318

Millsboro, DE 19966-0318

Generic Name of Drug: Fenbendazole

Trade Name: PANACUR®-C

Marketing Status: Over-the-Counter (OTC)

Effect of Supplement: This supplement provides for a change from prescription (Rx) to OTC status for fenbendazole granules 22.2% packets to be marketed under the trade name PANACUR®-C. The jar presentation (Panacur®) will remain prescription (Rx) as it is also labeled for use in other species of carnivorous/omnivorous animals. The jar presentation will continue to be marketed under the Panacur® trade name.

2. INDICATIONS FOR USE

PANACUR®-C granules are indicated for use in adult dogs (including pregnant bitches) and puppies, six weeks of age or older, for the treatment and control of roundworms (*Toxocara canis, Toxascaris leonina*), hookworms (*Ancylostoma caninum, Uncinaria stenocephala*), whipworms (*Trichuris vulpis*) and tapeworms (*Taenia pisiformis*).

3. DOSAGE FORM

Granules 22.2% (222 mg/g) for oral use

4. ROUTE OF ADMINISTRATION

PANACUR®-C granules should be mixed with a small amount of the usual food. Make sure the dog eats all of the medicated food. Dry dog food may need to be moistened to aid mixing.

5. RECOMMENDED DOSAGE

The daily dose for PANACUR®-C is 50 mg/kg (22.7 mg/lb.) of body weight. PANACUR®-C is packaged in three packet sizes (1g, 2g and 4g) for administration based on the weight of the dog (see Dosing Table below). Weigh the dog to make sure the right size and number of packets are used. If the dog's weight is in-between the suggested dosing sizes, it is safe to use the next higher size. For example, a 15-pound dog should be treated with the 2-gram packet. Packet size is the daily dose and the dog must be treated with this dose for three (3) days in a row.

Dosing Table

Dog Weight	Packet Size
10 pounds	1 gram
20 pounds	2 gram
30 pounds	1 gram + 2 gram
40 pounds	4 gram
50 pounds	1 gram + 4 gram
60 pounds	2 gram + 4 gram
80 pounds	Two 4 gram
Over 80 pounds	Use combinations to obtain recommended daily dose.

6. EFFECTIVENESS

The effectiveness of the product is not affected by this supplement. Refer to the FOI Summary for the original approval dated 27 October 1983.

7. SAFETY

The safety of this product is not affected by this supplement. Refer to the FOI Summary for the original approval dated 27 October 1983.

8. HUMAN SAFETY

Data on human safety pertaining to the consumption of drug residues in food were not required for approval of this supplemental NADA. The product is labeled for use in dogs, which are non-food animals.

9. AGENCY CONCLUSIONS

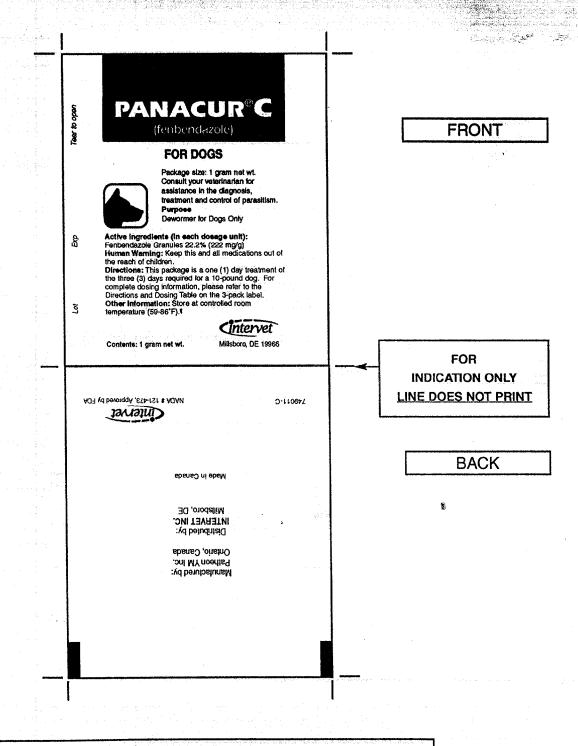
The data in support of this NADA comply with the requirements of Section 512 of the Act and Part 514 of the implementing regulations. The data demonstrate that Panacur (fenbendazole) Granules 22.2%, when used under labeled conditions is safe and effective.

At the time of original approval this drug product received prescription status because of concern that fenbendazole may have some undiscovered hepatotoxic effects in dogs. This concern was based on reports of liver disease associated with the use of oxibendazole and mebendazole in dogs. The restriction to prescription status was intended to assist in timely notification/documentation of such adverse reactions should they occur. Post-approval marketing experience has not demonstrated a pattern of liver disease associated with the use of Panacur (fenbendazole) Granules 22.2% in dogs. Since the safety concern has been satisfied, and adequate directions for safe and effective use can be written for the layman, there is no longer a need for prescription status for use of this product in dogs.

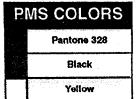
10. LABELING

PANACUR®-C – 1-gram packet label PANACUR®-C – 3 x 1-gram box label PANACUR®-C – 2-gram packet label PANACUR®-C – 3 x 2-gram box label PANACUR®-C – 4-gram packet label PANACUR®-C – 3 x 4-gram box label

Pg.2: <u>1 PIECE WEB</u>: W: 6^{9/16*} (1 GRAM)



6-00 • Panacur 1 gram Granule Pouch Label • Size: 2.3/4"x6.9/16" •





(fenbendazole)

FOR DOGS



Package contents: Three 1-gram packets Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Drug Facts Active ingredients (in each dosage unit): Fenbendazole Granules 22.2% (222 mg/g) Purpose: Dewormer for Dogs Only

Uses: For the treatment and control of Roundworms (Toxocara canis, Toxascaris Jeonina), Hookworms (Ancylostoma caninum, Uncinaria stenocephala), Whipworms (Trichuris vulpis), and Tapeworms

Human Warning: Keep this and all medication out of the reach of children

Adverse Reactions: In US clinical studies 3 of 240 dogs (about 1% of the treated dogs) had vomiting associated with use of the product.

When using this product: PANACUR® C is safe for use in pupples 6 weeks or older and adult dogs, including pregnant bltches. Do not deworm a dog or puppy that is sick. Consult your veterinarian for diagnosis of the illness.

Contents: Three 1-gram packets



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Expiration date:

Net Weight: 3 grams

Made in Canada

NALDA #123-473, Approved by HDA

Wilspoto, DE MI EHAFT INC. Distributed by:

Paineon YM Inc. Manufactured by:

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material selety data sheets (MSDS), call 1-800-328-5908. or report a suspected adverse reaction or to obtain product intermation including Questions? Comments?

Storage: Store at controlled room temperature (59-86'F).

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Degroesis, treatment, and control of paraetism. Dogs can become intecied with several different linds of tapeworms. It you confinue to see tapeworm segments in your dog's stool attent PANACURF C, consult your velerinarian.

Recommended Deworming Schedule: Deworming schedules may vary depending on the climate where you live and the commended Deworming Schedules. Deworming schedules. Deworming schedules are to be weeks of age, Irise to the dewormed sit lass the pupples. Dogs over six months of age should be dewormed at lass the united to age. The act of semestic schedules are the pupples. Dogs over all age should be dewormed at least white aschedules. Better the second time as the pupples. Dogs over all and the second time as the pupples. Dogs over the control of the second time as the pupples. Dogs over the second time as the pupples. Dogs over the control of the second time as the pupples. Dogs over the control of the second time as the pupples. Dogs over the control of the second time as the pupples. Dogs over the control of the second time as the pupples. Dogs over the control of the second time as the pupples. Dogs over the control of the second time at the second time

- · Repeat the daily dose for three days in a row.

• You should weigh your dog to make sure you are using the right size and number of packets. If you dog's weight is transfer a submount of the resumple, a 15-pound dog should be treated with the 2-gram packet.

• Give PANACUTP® C to your dog by mixing the delity dose with a small amount of the usual bood. Make sure your dog eats all of the maddested lood. You may need to moletien dry dog tood to sid mixing. *Packet size is the dally dose. The dog must be treated with this dose for 3 days in a row.

Use combinations to obtain tecommended daily dose.	Over 80 pounds
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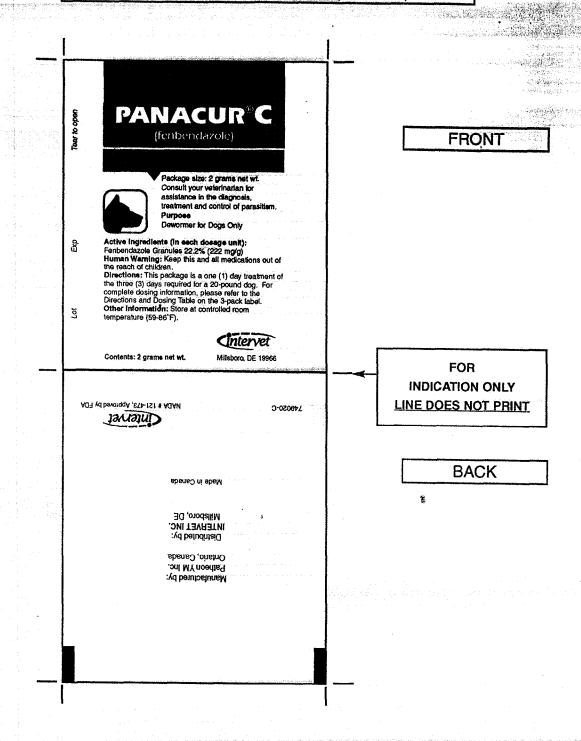
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Dog Weight Doeing Table

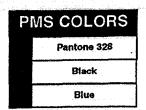
The daily dose for PANACURE C is 60 mg/kg (22.7 mg/b.) of body weight. Please refer to the following dosing table for



Pg.2: <u>1 PIECE WEB</u>: W: 69/16" (2 GRAM)



6-00 • Panacur 2 gram Granule Pouch Label • Size: 2.3/4"x6.9/16" •



PANACUR® C

(fenbendazole)



Package contents: Three 2-gram packets Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Active ingredients (in each dosage unit): Fenbendazole Granules 22.2% (222 mg/g) Purpose: Dewormer for Dogs Only

Uses: For the treatment and control of Roundworms (Toxocara canis, Toxascaris leonina), Hookworms (Ancylostoma caninum, Uncinaria stenocephala), Whipworms (Trichuris vulpis), and Tapeworms (Taenia pisitormis)

Human Warning: Keep this and all medication out of the reach of children.

Adverse Reactions: In US clinical studies 3 of 240 dogs (about 1% of the treated dogs) had vomiting associated with use of the product.

When using this product: PANACUR® C is safe for use in pupples 6 weeks or older and adult dogs, including pregnant bitches. Do not deworm a dog or puppy that is sick. Consult your veterinarian for diagnosis

Contents: Three 2-gram packets

Net Weight: 6 grams

Made in Canada

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Willsporo, DE Distributed by:

Ontario, Canada Patheon YM Inc. Manufactured by:



material safety data sheets (MSDS), call 1-800-328-5908. To report a suspected adverse reaction or to obtain product information including Questions? Comments?

Storage: Store at controlled room temperature (59-86°F).

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- Sive PANACURP C to your dog by mixing the daily dose with a small amount of the usual bod. Make sure your dog eats all of the medicated lock. You may need to moiston dry dog lood to eid mixing.
 Repeat the daily dose for three days in a row.
- treated with the 2-gram packet.

*Pecket elize is the dally does. The dog must be treated with this does for 3 days in a row.

• You should weigh your dog to make sure you are using the right size and number of peckets. If your dogs weight is in the behaven the suggested doeling sizes, it is sais to use the next higher size. For example, a 15-pound dog should be

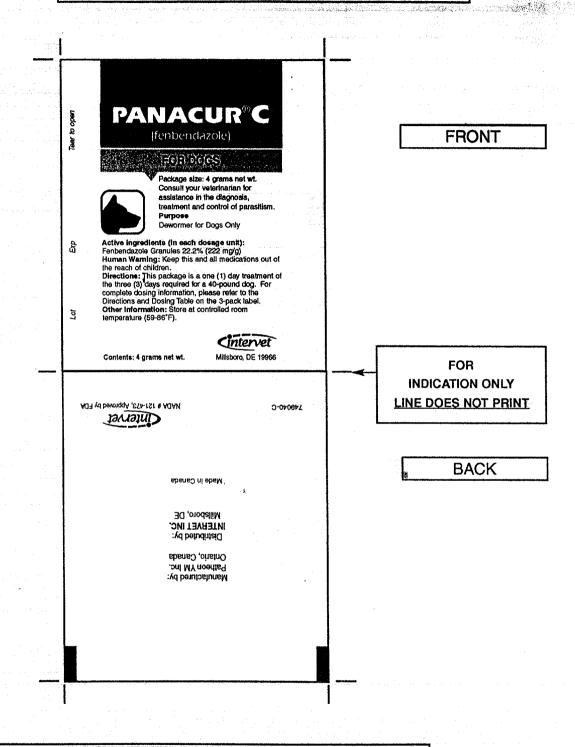
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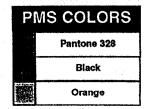
The daily dose for PANACUR® C is 50 mg/kg (22.7 mg/lb.) of body weight. Please refer to the following dosing table for following dose for your dose for your dose.

Pg.2: 1 PIECE WEB: W: 69/16" (4 GRAM)

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6-00 • Panacur 4 gram Granule Pouch Label • Size: 2.3/4"x6.9/16" •



PANACUR® C

(fenbendazole)

FOR DOGS



ackage contents: Three 4-gram packets Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Drug Facts Active ingredients (in each dosage unit): Fenbendazole Granules 22.2% (222 mg/g) Purpose: Dewormer for Dogs Only

Uses: For the treatment and control of Roundworms (Toxocara canis, Toxascaris leonina), Hookworms (Ancylostoma caninum, Uncinaria stenocephala), Whipworms (Trichuris vulpis), and Tapeworms

Human Warning: Keep this and all medication out of the reach of children.

Adverse Reactions: In US clinical studies 3 of 240 dogs (about 1% of the treated dogs) had vomiting associated with use of the product.

When using this product: PANACUR® C is safe for use in pupples 6 weeks or older and adult dogs. including pregnant bitches. Do not deworm a dog or puppy that is sick. Consult your veterinarian for diagnosis of the illness.

Contents: Three 4-gram packets

intervet

Expiration date:

Net Weight: 12 grams

Made in Canada

NADA #121-473, Approved by FDA

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Millsboro, DE INTERVET INC. Distributed by:

Manufactured by:

To report a suspected adverse reaction or to obtain product information including material safety data sheets (MSDS), call 1-800-328-5908. Guesnous Comments

Storage: Store at controlled room temperature (59-86°F).

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. Repeat the daily dose for three days in a row.

- eats all of the medicated boot. You may need to moisten dry dog boot to aid mixing.

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help in finding the right dose for your dog. The daily dose for PANACUH® C is 50 mg/kg (22.7 mg/b.) of body weight. Please refer to the following dosing table for